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Teva Pharmaceuticals Industries, Ltd.

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALTANA PHARMA AG, and WYETH

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.)

Defendants.

Civil Action No.: 04-2355 (JLL)

**TEVA PHARMACEUTICALS INDUSTRIES LTD.'S
ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Teva Pharmaceuticals Industries Ltd. (hereinafter "Teva Industries"), by its
attorneys, for its Answer responds as follows:

THE PARTIES

1. Teva Industries is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶1 of the Complaint and, therefore, denies them.

2. Teva Industries is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 2 of the Complaint and, therefore, denies them.

3. Paragraph 3 is not a factual or legal allegation and requires no response.

4. Paragraph 4 is not directed to Teva Industries and requires no response. Teva Industries cannot speak for Teva Pharmaceuticals USA, Inc. ("Teva USA"). Therefore, to the extent that any of the allegations in the Complaint pertain to Teva USA, Teva Industries denies them. To the extent not admitted, Teva Industries denies the remaining allegations found in ¶ 4.

5. Admitted.

6. Teva Industries admits that it has a subsidiary, Teva USA, and that there is some overlap in the directors and/or officers of the two companies. To the extent not admitted, Teva Industries denies the remaining allegations found in ¶ 6 of the Complaint.

7. Teva Industries denies the allegations in ¶ 7 of the Complaint.

8. Paragraph 8 is not a factual or legal allegation and requires no response.

9. Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 9 of the Complaint and, therefore, denies them.

10. Admitted.

11. Teva Industries admits that this purports to be a civil action arising under the patent laws of the United States of America. As to the remaining allegations contained in this paragraph, denied with respect to Teva Industries. As to Teva USA, Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 11 of

the Complaint and, therefore, denies them.

12. Upon information and belief, Teva Industries admits that New Drug Application No. 20-987 was approved by the United States Food & Drug Administration for 20 mg and 40 mg delayed-release tablets including the active ingredient pantoprazole sodium. Upon information and belief, Teva Industries admits that tablets including pantoprazole are promoted in the United States under the trade name “PROTONIX®”. To the extent not admitted, Teva Industries is without information sufficient for relief as to the truth or falsity of the remaining allegations found in ¶ 12 and, therefore, denies them.

13. Teva Industries admits claim 1 of the ‘579 patent claims a dialkoxypyridine. The remaining claims speak for themselves. Teva Industries is without information sufficient to form a belief as to the truth or falsity of the remaining allegations found in ¶ 13 of the Complaint and, therefore, denies them.

14. Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 14 of the Complaint and, therefore, denies them.

15. Teva Industries admits that a copy of the ‘579 patent was attached as Exhibit A to the Complaint.

16. Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 16 of the Complaint and, therefore, denies them.

17. Teva Industries admits that in the event Teva USA requires pantoprazole sodium tablets, Teva Israel is the presently intended manufacturer for those tablets. Teva Industries is without sufficient information to form a belief as to the truth or falsity of the remaining allegations found in ¶ 17 of the Complaint and, therefore, denies them.

18. Denied with respect to Teva Industries. As to Teva USA, Teva Industries is

without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 18 of the Complaint and, therefore, denies them.

19. Teva Industries is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 19 of the Complaint and, therefore, denies them.

20. Teva Industries is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 20 of the Complaint and, therefore, denies them.

21. Denied with respect to Teva Industries. As to Teva USA, Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 21 of the Complaint and, therefore, denies them.

22. Teva Industries denies the allegations in ¶ 22 of the Complaint.

23. Denied with respect to Teva Industries. As to Teva USA, Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 23 of the Complaint and, therefore, denies them.

24. Denied with respect to Teva Industries. As to Teva USA, Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 24 of the Complaint and, therefore, denies them.

25. Denied with respect to Teva Industries. As to Teva USA, Teva Industries is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 25 of the Complaint and, therefore, denies them.

26. Teva Industries denies the allegations in ¶ 26 of the Complaint.

PRAYER FOR RELIEF

27. In response to Plaintiffs' prayer for relief in the Complaint:

a. Teva Industries denies that Plaintiffs are entitled to the relief requested in

¶ 27(a) of the Prayer for Relief.

b. Teva Industries denies that Plaintiffs are entitled to the relief requested in

¶ 27(b) of the Prayer for Relief.

c. Teva Industries denies that Plaintiffs are entitled to the relief requested in

¶ 27(c) of the Prayer for Relief.

d. Teva Industries denies that Plaintiffs are entitled to the relief requested in

¶ 27(d) of the Prayer for Relief.

e. Teva Industries denies that Plaintiffs are entitled to the relief requested in

¶ 27(e) of the Prayer for Relief.

f. Teva Industries denies that Plaintiffs are entitled to the relief requested in

¶ 27(f) of the Prayer for Relief.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

28. Teva Industries will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271.

SECOND AFFIRMATIVE DEFENSE

29. Upon information and belief, the claims of the '579 patent are invalid under 35 U.S.C. § 103.

PRAYER FOR RELIEF

WHEREFORE, Teva Industries prays that the Court enter:

- A. A judgment that Teva Industries will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271;
- B. A judgment that the '579 patent is invalid;
- C. An Order enjoining and restraining Altana and Wyeth and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from further charges of infringement or acts of enforcement based on the '579 patent against Teva Industries or its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with Teva Industries; and
- D. An Order awarding Teva Industries such other further relief as the Court deems just and equitable.

LITE DEPALMA GREENBERG & RIVAS, LLC

Dated: September 27, 2004

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